

REMARKS

Status of the Claims

Claims 48-67 and 70-83 are currently pending in the application. Claims 48-51, 53-66 and 67-71 stand rejected. The Examiner objects to claims 52 and 66. Claims 52 and 66 have been amended as set forth herein. Claims 68 and 69 have been cancelled herein without prejudice or disclaimer. All amendments and cancellations are made without prejudice or disclaimer. New claims 72-83 have been added herein. No new matter has been added by way of the present amendments. The amendments to claims 52 and 66 are supported by at least claims 48 and 63, respectively.

New claim 72 is supported by claim 49.

New claim 73 is supported by claim 53.

New claim 74 is supported by claim 54.

New claim 75 is supported by claim 55.

New claim 76 is supported by claim 57.

New claim 77 is supported by claim 58.

New claim 78 is supported by claim 67.

New claims 79 and 80 are supported by claim 68.

New claim 81 is supported by claim 69.

New claim 82 is supported by claim 70.

New claim 83 is supported by claim 71.

Reconsideration is respectfully requested.

Objections to the Claims

The Examiner objects to claims 52 and 66 for depending on a rejected base claim. (*See*, Office Action of April 9, 2007, at page 2, hereinafter, "Office Action"). Although not stated by the Examiner, it is believed that if these claims were re-written in independent form to recite all of the limitations of the base claims from which they depend, and all intervening claims, they would be in condition for allowance. Thus, claims 52 and 66 have been amended herein without prejudice or disclaimer to recite all of the limitations of the base claims, claims 48 and 63, respectively, from which they depend. Applicants believe these amendments place these claims, and any claim depending therefrom, in condition for allowance, i.e. claims 58-62 and 72-83.

Thus, reconsideration and withdrawal of the objection to claims 52 and 66 are respectfully requested.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 48-51, 53-65 and 67-71 stand rejected under 35 U.S.C. § 112, first paragraph, for failing to comply with the enablement requirement. (*See*, Office Action, at page 3). Claims 68 and 69 have been cancelled herein without prejudice or disclaimer, thus obviating the rejection of these claims. Applicants traverse the rejection as to the remaining claims as follows.

The Examiner's position is essentially that, since methods for gene targeting through homologous recombination were not known in the art for plant species other than *Chlamydomonas* at the time of filing, undue experimentation would be required by one skilled in the art to use the claimed method to confer resistance to PPO-inhibiting herbicides upon all plants or plant cells. (*See*, Office Action of January 16, 2003, at page 12). The Examiner states

that "Puchta discusses how the frequency in plants is low enough that gene targeting is not feasible, which indicates that such techniques were not known in the prior art" and that "Terada et al. also discuss flaws of previous reports on homologous recombination." (See, Office Action of April 9, 2007, at page 3). The Examiner further states that it was known in 2005 whether the nucleic acid of the instant invention could produce PPO-resistant crops, since Li et al. discuss the same mutant *Chlamydomonas reinhardtii* mutation as discussed in the instant specification and since Li et al. state "It would be interesting to know whether this mutant PPO gene can be used to develop PPO-resistant crops." (See, *Id.*).

However, as reported by Puchta and Terada et al., there were several publications disclosing homologous recombination performed in plants at the time of the instant invention. Li et al. exhibit their interest in the same mutant *Chlamydomonas reinhardtii* mutation as discussed in the instant specification and do not deny the possibility that this mutant PPO gene can be used to develop PPO-resistant crops.

Further, in contrast to the Examiner's perception of the state of the art, Applicants submit that the technology the Examiner claims is lacking enablement was clearly within the capabilities of one of ordinary skill in the art as exemplified by publications indicative of the art, for instance, Offringa et al., U.S. Patent No. 5,501,967, which discloses a method for site-directed integration of DNA-sequence into the genome of plants *via* homologous recombination, which was deemed enabled by the Office on the date this application was filed, July 6, 1993.

Thus, it is clear that the Examiner is here applying an incorrect standard of review for prosecution of patents by an Administrative Agency. The Examiner appears to be reviewing the present application under a clear and convincing evidence standard, whereas legal precedent

clearly holds that prosecution of patent applications should be conducted only under the preponderance of the evidence standard of review. (See, *In re Zurko*, 258 F.3d 1379, 59 U.S.P.Q.2d 1693 (Fed. Cir. 2001), *see also*, *In re Gartside*, 203 F.3d 1305, 53 U.S.P.Q.2d 1769, 1773-1774 (Fed. Cir. 2000)). Under the proper preponderance of the evidence standard, or substantial evidence standard, Applicants' data of record adequately supports a finding of enablement of the presently pending claims.

The Examiner's attention is also respectfully directed to *In re Wands*, 8 U.S.P.Q.2d 1400 (Fed. Cir. 1988). In *In re Wands*, an invention related to the isolation of hybridomas that secreted a specific antibody was deemed broadly enabled despite the fact that extensive screening of many cloned cell lines was necessary including experiments that failed to generate any operable clones. The *Wands* court expressly stated that experimentation, such as the screening experiments described in the present application, which is expected to be performed by the artisan of ordinary skill, is not considered to be "undue experimentation."

Accordingly, the Examiner has the burden of showing that the application is nonenabling (i.e., that it does not teach how to make and use the invention). As stated by the Federal Circuit:

When rejecting a claim under the enablement requirement of Section 112, the [Patent Office] bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. *In re Wright*, 999 F.2d 1557, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993).

The Examiner has provided nothing more than conclusory statements with respect to non-enablement. Such conclusory statements, without any reasoning or analysis, do not support a

prima facie case of non-enablement. Thus, the burden remains on the Examiner to establish non-enablement of the presently claimed invention. Applicants have sufficiently rebutted the Examiner's premise of the enablement rejection by citation to publications clearly evidencing the knowledge of one of ordinary skill in the art and the state of the art at the time the present application was filed. Therefore the presently claimed invention, as recited in the pending claims, should be allowed.

The Examiner is also respectfully reminded that, "As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied." (*See, In re Fisher*, 427 F.2d 833, 839, 166 U.S.P.Q. 18, 24 (CCPA 1970)). Furthermore, Applicants point out that a "patent need not teach, and preferably omits, what is well known in the art." (*See, Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534 (Fed. Cir. 1987)).

Therefore, for at least these reasons, reconsideration and withdrawal of the enablement rejection of claims 48-51, 53-65, 67, 70 and 71 are respectfully requested.

CONCLUSION


If the Examiner has any questions or comments, please contact Thomas J. Siepmann, Ph.D., Registration No 57,374, at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

By

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